

SPECIFICATION AMENDMENTS

Please amend the Abstract as follows:

A medical lead and method of treating a patient are provided. The medical lead comprises an electrically insulative membrane, a resilient spring element associated with the insulative membrane, and at least one electrode associated with the insulative membrane. The spring layer is configured to urge that insulative membrane into an expanded geometry. The medical lead is configured to be collapsed into a compact form for percutaneous delivery into the patient, thereby obviating the need to perform an invasive surgical procedure on the patient. ~~The body formed by these elements, when expanded, can be sized to fit within the epidural space of a patient.~~ The patient can be treated by placing the medical lead into a collapsed state by applying a compressive force to the medical lead, percutaneously delivering the collapsed medical lead into the patient adjacent tissue to be treated, and placing the medical lead into an expanded state by releasing the compressive force. ~~In one preferred method, the stimulation lead is used to stimulate tissue, such as spinal cord tissue.~~

Please amend the paragraph beginning on page 1, line 5 to read:

This application is related to copending U.S. Patent Application Ser. No. ~~10/xxx,xxx~~  
(~~attorney docket number 30-7038152001~~) 10/799,295 filed on the same date, and expressly incorporated herein by reference.

Please amend the paragraph beginning on page 9, line 12 to read:

The stimulation lead 102 comprises an elongated sheath body 108 having a proximal end 110 and a distal end 112. The sheath body 108 is composed of a suitably flexible material (such as polyurethane, silicone, etc.), which may either be resilient or non-resilient, and may be formed via an extrusion process or by any other suitable means. In the illustrated embodiment, the sheath body

108 is cylindrically-shaped and sized to fit through a Touhy-like needle (not shown). In this case, the diameter of the sheath body 108 is preferably less than 5 mm to allow it to be percutaneously introduced through a needle. More preferably, the diameter of the sheath body 108 is within the range of 1 mm to 3 mm, so that the stimulation lead 102, ~~along with the secondary stimulation leads 104 described below,~~ can comfortably fit within the epidural space of the patient. The sheath body 108 may have other cross-sectional geometries, such as oval, rectangular, triangular, etc. If rectangular, the width of the stimulation lead 102 can be up to 5 mm, since the width of an epidural space is greater than its height. The sheath body 108 may have an optional lumen (not shown) for receiving an obturator (not shown) that axially stiffens the sheath body 108 to facilitate percutaneous introduction of the stimulation lead 102 within the epidural space of the patient's spine, as will be described in further detail below.

Please amend the paragraph beginning on page 14, line 15 to read:

As another example, **Fig. 9** illustrates a stimulation paddle 136 having a skeletal spring element 122 that includes a main spring segment 144 that extends longitudinally along the centerline of the membrane 118, and a plurality of lateral spring segments 145 that branch off of the main spring segment 144 between the electrodes 120. As can be seen in **Fig. 9**, the electrodes 120 are arranged as two columns of four elements each extending down the lateral sides of the membrane 118. Besides providing a structure from which the lateral spring segments ~~144~~ 145 are supported, the main spring segment 144 provides axial stiffness to the stimulation paddle ~~146~~ 136, thereby facilitating axial movement (i.e., the pushability) of the expanded stimulation paddle 146 by minimizing axial buckling of the membrane 118. To this end, the main spring segment 144 is somewhat wider than the lateral spring segments 145. The lateral spring segments 145 act as cross-

members that urge the membrane 118 into its normally expanded state, thereby providing the spring force that transforms the collapsed membrane 118 into the expanded geometry in the absence of a compressive force.

Please amend the paragraph beginning on page 15, line 5 to read:

**Fig. 10** illustrates a stimulation paddle 146 that comprises a skeletal spring element 152, which is similar to the previously described spring element ~~152~~ 142, with the exception that it comprises lateral staggered spring segments 155 that are not linear, but are rather formed into two dimensional shapes—in this case a leaf shape. This increased size of the lateral spring segments 155 provides increased lateral spring force to the stimulation paddle 146. In this case, the number of lateral segments 155 are decreased, and the electrodes 120 are arranged into two columns of two elements each.

Please amend the paragraph beginning on page 15, line 21 to read:

**Fig. 12** illustrates a stimulation paddle 166 that comprises a skeletal spring element 172 with a trunk segment 173, two main spring segments 174 that longitudinally extend from the trunk segment 173 along the left and right lateral sides of the membrane 118, and lateral spring segments 175 that branch off of the main spring segments 174 towards the midline of the membrane 118. Like the main spring segment 144 of the stimulation paddle 136 illustrated in **Fig. 9**, the main spring segments 174 provide axial rigidity to the stimulation paddle 166, while providing a structure supporting the lateral spring segments 175. Like the lateral spring segments ~~175~~ 145 of the stimulation paddle ~~166~~ 136 illustrated in **Fig. 11** ~~9~~, the lateral spring segments 175 act as cross members that facilitate transformation of the stimulation paddle 166 from its collapsed geometry into its expanded geometry. To prevent inadvertent perforation of the insulative membrane 118, the

distal ends of the main spring segments 174 and secondary spring segments 175 are beaded. The electrodes 120 are arranged in a single column of four electrodes 120 extending down the midline of the membrane 118 between the respective secondary spring segments 175.

Please amend the paragraph beginning on page 19, line 7 to read:

Referring back to **Fig. 1**, the implantable stimulation source 104 is designed to deliver electrical pulses to the stimulation lead 102 in accordance with programmed parameters. In the preferred embodiment, the stimulation source 104 is programmed to output electrical pulses having amplitudes varying from 0.1 to 20 volts, pulse widths varying from 0.02 to 1.5 milliseconds, and repetition rates varying from 2 to 2500 Hertz. In the illustrated embodiment, the stimulation source 104 takes the form of a totally self-contained generator, which once implanted, may be activated and controlled by an outside telemetry source, e.g., a small magnet. In this case, the pulse generator has an internal power source that limits the life of the pulse generator to a few years, and after the power source is expended, the pulse generator must be replaced. Generally, these types of stimulation sources ~~106~~ 104 may be implanted within the chest or abdominal region beneath the skin of the patient.

Please amend the paragraph beginning on page 19, line 19 to read:

Alternatively, the implantable stimulation source 104 may take the form of a passive receiver that receives radio frequency (RF) signals from an external transmitter worn by the patient. In this scenario, the life of the stimulation source 104 is virtually unlimited, since the stimulation signals originate from the external transmitter. Like the self-contained generators, the receivers of these types of stimulation sources ~~106~~ 104 can be implanted within the chest or abdominal region beneath the skin of the patient. The receivers may also be suitable for implantation behind the ear of the

patient, in which case, the external transmitter may be worn on the ear of the patient in a manner similar to that of a hearing aid. Stimulation sources, such as those just described, are commercially available from Advanced Neuromodulation Systems, Inc., located in Plano, Texas, and Medtronic, Inc., located in Minneapolis, Minnesota.

Please amend the paragraph beginning on page 20, line 6 to read:

The optional extension lead 106 comprises an elongated sheath body 109 having a proximal end 111 and a distal end 113, much like the sheath body 108 of the stimulation lead 102, a proximal connector 115 coupled to the proximal end ~~113~~ 111 of the sheath body 109, a distal connector 117 coupled to the distal end ~~111~~ 113 of the sheath body 109, and a plurality of electrical conductors (not shown) extending through the sheath body 109 between the proximal and distal connectors 115/117. The length of the extension lead 102 is sufficient to extend from the spine of the patient, where the proximal end of the implanted stimulation lead 102 protrudes from to the implantation site of the stimulation source 104—typically somewhere in the chest or abdominal region. The proximal connector 115 is configured to be coupled with to the stimulation source 104, and the distal connector 117 is configured to mate with the proximal end of the stimulation lead 102.

Please amend the paragraph beginning on page 21, line 23 to read:

Next, the needle 10 or introducer is removed, and the proximal end of the stimulation lead 102 is connected to a tester (not shown), which is then operated in a standard manner to confirm proper location of the stimulation lead 102 and to adjust the stimulation parameters for optimal pain relief. Once this optimization process has been completed, the tester is disconnected from the stimulation lead 102, which is then anchored in place using standard lead anchors (not shown). In the case of stimulation tubes 216/236, anchors may not be necessary, since they self-anchor

themselves within the epidural space when expanded. Next, the stimulation lead 102 is coupled to the stimulation source 104 and implantation is completed (not shown). In particular, a subcutaneous pocket is created in the patient's abdominal area for implantation of the stimulation source 104, and a tunnel is subcutaneously formed between the spine region and the subcutaneous pocket. The optional lead extension 106 is passed through the tunnel, after which the ~~adapter 154~~ distal connector 117 of the extension 106 is connected to the proximal end of the stimulation leads 102 and the ~~proximal connector 156~~ proximal connector 115 of the lead extension 106 is connected to the stimulation source 104. The stimulation source 104 is programmed and tested, and then placed within the subcutaneous pocket, after which all incisions are closed to effect implantation of the stimulation lead 102 and stimulation source 104. The stimulation source 104 can then be operated to convey stimulation energy from the stimulation source 104 to the electrodes 120 of the stimulation lead 102, where it is, in turn, conveyed into the neural tissue for pain relief.